

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

BROOKLYN OFFICE

-----X
Ali Elbaneh and Subhia Elbaneh,

Plaintiffs,

Civil Action No.:

CV11 - 2680

v.

**COMPLAINT AND
DEMAND FOR JURY TRIAL**

ZIMMER HOLDINGS, INC; ZIMMER
ORTHOPAEDIC SURGICAL PRODUCTS, INC.,
ZIMMER ORTHOBIOLOGICS, INC.,

VITALIANO, J.

Defendant.
-----X

J. ORENSTEIN, M.J.

COMES NOW the Plaintiffs, Ali Elbaneh and Subhia Elbaneh, by and through
their undersigned Counsel, and for their Complaint against the Defendants, allege as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Ali Elbaneh, as a direct and proximate result of Defendants' wrongful conduct in connection with the development, design, manufacture, distribution, and selling of Defendants' knee replacement product, the Zimmer NexGen Legacy Posterior Stabilized High-Flex knee replacement with an CR-Flex Femoral Component (hereinafter "Zimmer NexGen CR Flex") or "the Product".

2. Defendants knew or should have known that the Zimmer NexGen CR Flex can loosen in patients, such as Plaintiff Ali Elbaneh, causing personal injury, significant pain, and loss of movement, and that this injury can only be remedied through subsequent revision surgery.

3. Further, Defendants misled health care professionals and the public into believing that the Zimmer NexGen CR Flex was safe and effective for use in knee replacement surgery; engaged in deceptive, misleading and unconscionable promotional or sales methods to convince

health care professionals to utilize the Zimmer NexGen CR Flex, even though Defendants knew or should have known that the Zimmer NexGen CR Flex was unreasonably unsafe; and failed to warn health care professionals and the public about the safety risks of the Zimmer NexGen CR Flex.

PARTIES

4. Plaintiff Ali and Subhia Elbaneh are citizens of the State of New York, and residents of Buffalo, New York.

5. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana.

6. Defendant Zimmer Orthobiologics, Inc. is a corporation organized and existing under the laws of New Jersey, and has its principal place of business in Warsaw, Indiana.

7. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized and existing under the laws of Ohio, and has its principal place of business in Dover, Ohio.

8. At all times material hereto, Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer NexGen CR Flex. Defendants' products, including the Zimmer NexGen CR Flex, are sold throughout the world, including within the state of New York.

JURISDICTION AND VENUE

9. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds \$75,000 exclusive of interest and costs.

10. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. § 1391.

FACTUAL BACKGROUND

KNEE REPLACEMENT BACKGROUND

11. Total knee arthroplasty (TKA), also called total knee replacement, is a common medical procedure performed. The surgery is designed to help relieve pain and improve joint function in people with severe knee degeneration due to arthritis or trauma.

12. Upon information and belief, the TKA procedure is done by separating the muscles and ligaments around the knee to expose the inside of the joint. The ends of the thigh bone (femur) and the shin bone (tibia) are removed as is often the underside of the kneecap (patella).

13. Upon information and belief, about 85 to 90 percent of total knee replacements are successful up to ten years.

14. Mechanical loosening means that for some reason (other than infection) the attachment between the artificial knee and the bone has become loose.

15. Loosening can occur with any component of the artificial knee: the femoral, the tibial or the patellar component.

16. Upon information and belief, loosening of an artificial knee can be diagnosed using X-ray. X-ray pictures of a loose knee joint there are one or more radiolucent lines around the contours of the artificial knee joint.

17. A loose artificial knee is a problem because it causes pain and wearing away of the bone. A painful loose knee can restrict the patient's daily activities severely. A loose artificial knee also involves severe psychological burden for the patient.

18. Once the pain becomes unbearable or the individual loses function of the knee, another operation will probably be required to revise the knee replacement. A loose, painful artificial knee can usually, but not always, be replaced.

19. The purpose of knee revision surgery is to remove a failed knee implant and replace it with a new one.

20. Upon information and belief, in a revision operation of a total knee failed by loosening the biggest problem is usually to reconstruct the severe bone loss caused by bone destruction around the failed total knee prosthesis, and restore the stability in the revised total knee.

21. Upon information and belief, the results of a revision operation are not as good as the first, and the risks of complications are higher. The range of motion in the knee after the revision surgery may be smaller and the walking capacity may be also diminished. The rate of loosening is higher after revision surgery than in primary knee replacement surgery.

ZIMMER NEXGEN CR FLEX FACTS

22. Zimmer was founded in 1927, and purports to be a worldwide leader in the design and manufacture of orthopaedic reconstructive, spinal and trauma devices, dental implants, and related orthopaedic surgical products.

23. The Zimmer NexGen CR Flex uses a “high-flex” femoral component that purports to allow a greater degree of flexion than the standard femoral component.

24. The Defendants generally, manufactured, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part and parcel of the sale and distribution of the medical device, and by said activities, caused the Zimmer NexGen CR Flex to be placed into the stream of commerce throughout the United States.

25. Defendants made, participated in and/or contributed to filings with the FDA in conjunction with the approval process for the Zimmer NexGen CR Flex.

26. Upon information and belief, Defendants was in control of the design, assembly, manufacture, marketing, distribution, packaging, labeling, processing, supplying, promotion, sales, and the issuance of product warnings and related information with respect to the Zimmer NexGen CR Flex.

27. Defendants was at all times material hereto subject to the laws of the United States of America, including provisions relating to the FDA, and the rules and regulations thereof, in conjunction with the approval process, labeling, and other after-market activities that pertain to the Zimmer NexGen CR Flex.

28. The Zimmer NexGen CR Flex has been widely advertised, marketed and represented by the Defendants as a safe and effective device.

ZIMMER NEXGEN CR FLEX PROBLEMS

29. In 2010, Dr. Richard A. Berger, a Zimmer consultant, and his colleague Dr. Craig J. Della Valle, presented a paper at a national meeting of the American Association of Orthopedic Surgeons showing that approximately 9% percent of their patients who had the Zimmer NexGen Knee implanted required revision surgery and 36% showed signs of the knee implant loosening within one year of implant.

30. From the time that Defendants first began selling the Zimmer NexGen CR Flex in the United States, the product labeling and product information for the Zimmer NexGen CR Flex failed to contain adequate information, instructions, and warnings concerning implantation of the product and the increased risks that the Zimmer NexGen CR Flex can loosen in patients.

31. Despite its knowledge of the serious injuries associated with use of the Zimmer NexGen CR Flex, Defendants engaged in a marketing and advertising program which as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Zimmer NexGen CR Flex was safe.

32. Upon information and belief, Defendants downplayed and understated the health hazards and risks associated with the use of the Zimmer NexGen CR Flex and through promotional literature as well as sales visits to orthopaedic surgeons, deceived doctors and potential users of the Zimmer NexGen CR Flex by relaying positive information, while concealing the nature and extent of known adverse and serious health effects.

FACTUAL ALLEGATIONS

33. On February 11, 2009, Plaintiff's physician implanted a Zimmer NexGen CR Flex system including a NexGen CR High Flex femoral component.

34. Prior to February 11, 2009, the treating physicians for Plaintiff, as well as Plaintiff, were exposed to the aforementioned advertising and marketing campaign directly by the Defendants.

35. Plaintiff Ali Elbaneh and Plaintiff's physician, either through direct promotional contact with Sales Representative Defendants, through word-of-mouth from other health care providers, and/or through promotional materials, received the information the Defendants intended that they receive, to-wit: that the Zimmer NexGen CR Flex was safe and effective for use in TKA procedures.

36. Plaintiff returned to Plaintiff's physician several times due to consistent pain relating to his Zimmer NexGen CR Flex and on or around January of 2010 was advised that he would need revision surgery for his Zimmer NexGen CR Flex.

37. On June 23, 2010, Plaintiff had a second surgery to revise/replace his previously implanted Zimmer NexGen CR Flex. Plaintiff's entire artificial knee system was replaced.

38. As a direct and proximate result of the use of the Zimmer NexGen CR Flex, Plaintiff suffered, and continues to suffer, serious bodily injury and harm.

39. As a direct and proximate result of the use of the Zimmer NexGen CR Flex, Plaintiff incurred, and continues to incur, medical expenses to treat his injuries and condition.

40. At no time material to his use of the Zimmer NexGen CR Flex was Plaintiff or his physicians told, warned, or given information about the higher risks of loosening in the Zimmer NexGen CR Flex.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

41. The running of any statute of limitations has been tolled by reason of Defendant's fraudulent concealment. Defendant, through its affirmative misrepresentations and omissions, actively concealed from plaintiff and plaintiff's operating physician the true risks associated with utilizing the Zimmer NexGen CR Flex.

42. As a result of Defendant's actions, plaintiff and plaintiff's physician were unaware, and could not reasonably know or have learned through reasonable diligence that plaintiff had been exposed to risks alleged herein and that those risks were the direct and proximate result of Defendant's acts and omissions.

43. Furthermore, the defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of the Zimmer NexGen CR Flex. The defendants were under a duty to disclose the true character, quality and nature of Zimmer NexGen CR Flex because this was non-public information over which the defendants had and continue to have exclusive control, and because the defendants

knew that this information was not available to the plaintiffs, medical providers and/or to their facilities. In addition, the defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

44. The plaintiff had no knowledge that the defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the defendants, the plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. The defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable medical device, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the defendants' representations.

COUNT I

(STRICT LIABILITY)

45. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

46. At all relevant times hereto, Defendants were engaged in the development, testing, manufacturing, marketing and sales of Zimmer NexGen CR Flex. Defendants designed, manufactured, marketed, and sold Zimmer NexGen CR Flex to medical professionals and their patients, knowing it would be implanted for knee replacements.

47. Zimmer NexGen CR Flex as designed, manufactured, marketed and sold by Defendants reached Plaintiff without substantial change in its condition and was used by Plaintiff in a reasonably foreseeable and intended manner.

48. Zimmer NexGen CR Flex was “defective” and “unreasonably dangerous” when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that Zimmer NexGen CR Flex was in a condition not suitable for their proper and intended use among patients.

49. The Zimmer NexGen CR Flex was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.

50. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable care, the defective nature of the Zimmer NexGen CR Flex. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the Zimmer NexGen CR Flex in such a way as to increase the risk of harm or injury to the recipients of it.

51. The Zimmer NexGen CR Flex is defective in design because of its propensity to loosen and cause patients unnecessary pain and repeat surgical procedures.

52. The Zimmer NexGen CR Flex is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, inter alia, the propensity of Zimmer NexGen CR Flex to loosen and cause serious pain and necessitate additional surgery; the post-marketing experience of higher rates of loosening and revision surgery with the Zimmer NexGen CR Flex; and the probability of suffering loosening and revision surgery.

53. Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, even though such products were feasible and marketable at the time Defendants sold Zimmer NexGen CR Flex to Plaintiff.

54. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer NexGen CR Flex. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and his physicians that Zimmer NexGen CR Flex causes serious injuries including, loosening and revision surgery.

55. As a direct and proximate result of Defendants' wrongful conduct, including Zimmer NexGen CR Flex's defective and dangerous design and inadequate warnings, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which he is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

56. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II

(PRODUCTS LIABILITY – FAILURE TO WARN)

57. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

58. Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer NexGen CR Flex and, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, or persons

responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer NexGen CR Flex.

59. Defendants failed to adequately warn health care professionals and the public, including Plaintiff Ali Elbaneh and his prescribing physician, of the true risks of the Zimmer NexGen CR Flex, including that the Zimmer NexGen CR Flex could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

60. Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer NexGen CR Flex. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physician, would have prescribed the Zimmer NexGen CR Flex, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer NexGen CR Flex.

61. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer NexGen CR Flex. Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer NexGen CR Flex, without causing serious pain and injury to patients, including Plaintiff.

62. The Zimmer NexGen CR Flex, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer NexGen CR Flex and knee replacement loosening causing serious injury and pain. Defendants failed to provide

adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Zimmer NexGen CR Flex.

63. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

64. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiff suffered serious and permanent non-economic and economic injuries.

65. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III

(PRODUCTS LIABILITY – DEFECTIVE DESIGN)

66. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

67. Defendants is the researcher, developer, manufacturer, distributor, marketer, promoter, supplier and seller of the Zimmer NexGen CR Flex, which is defective and unreasonably dangerous to consumers.

68. The Zimmer NexGen CR Flex is defective in its design or formulation in that it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The Zimmer NexGen CR Flex is defective in design or formulation in that it lacks efficacy and/or it poses a greater likelihood of injury than other knee replacement devices and similar knee replacement devices on the market and is more dangerous than ordinary consumers can reasonably foresee.

69. If the design defect were known at the time of manufacture, a reasonable person would have concluded that the utility of the Zimmer NexGen CR Flex did not outweigh the risk of marketing a product designed in that manner.

70. The defective condition of the Zimmer NexGen CR Flex rendered it unreasonably dangerous and/or not reasonably safe, and the Zimmer NexGen CR Flex was in this defective condition at the time it left the hands of the Defendants. The Zimmer NexGen CR Flex was expected to and did reach consumers, including Plaintiff Ali Elbaneh, without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied and otherwise released into the stream of commerce.

71. Plaintiff and her physician were unaware of the significant hazards and defects in the Zimmer NexGen CR Flex.

72. The Zimmer NexGen CR Flex was unreasonably dangerous and/or not reasonably safe in that it was more dangerous than would be reasonably contemplated by the ordinary user. During the period that Plaintiff used the Zimmer NexGen CR Flex, it was being utilized in a manner that was intended by Defendants.

73. At the time Plaintiff received and used the Zimmer NexGen CR Flex, it was represented to be safe and free from latent defects.

74. Defendants is strictly liable to Plaintiff for designing, manufacturing, and placing into the stream of commerce a product which was unreasonably dangerous for its reasonably foreseeable uses at the time it left the control of Defendants because of the design defects.

75. Defendants knew or should have known of the danger associated with the use of the Zimmer NexGen CR Flex, as well as the defective nature of the Zimmer NexGen CR Flex, but has continued to design, manufacture, sell, distribute, market, promote and/or supply the

Zimmer NexGen CR Flex so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Zimmer NexGen CR Flex.

76. As a direct and proximate cause of the design defect and Defendants' misconduct as set forth herein, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries.

77. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IV
(NEGLIGENCE)

78. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

79. At all relevant times, Defendants had a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of Zimmer NexGen CR Flex, including a duty to ensure that Zimmer NexGen CR Flex did not pose a significantly increased risk of bodily injury to its users.

80. Defendants had a duty to exercise reasonable care in the advertising and sale of Zimmer NexGen CR Flex, including a duty to warn Plaintiff and other consumers, of the dangers associated with the consumption of Zimmer NexGen CR Flex that were known or should have been known to Defendants at the time of the sale of Zimmer NexGen CR Flex to the Plaintiff.

81. Defendants failed to exercise reasonable care in the design, testing, manufacture, marketing, sale and distribution of Zimmer NexGen CR Flex because Defendants knew or

should have known that Zimmer NexGen CR Flex had a propensity to cause serious injury, including loosening and revision surgery

82. Defendants failed to exercise ordinary care in the labeling of Zimmer NexGen CR Flex and failed to issue adequate pre-marketing or post-marketing warnings to prescribing doctors and the general public regarding the risk of serious injury, including, loosening and revision surgery.

83. Defendants knew or should have known that Plaintiff could foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

84. Defendants breached their duty of reasonable care to Plaintiff by failing to exercise due care under the circumstances.

85. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer NexGen CR Flex, Plaintiff was implanted with Zimmer NexGen CR Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

86. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V

(BREACH OF EXPRESS WARRANTY)

87. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

88. Defendants advertised, labeled, marketed and promoted its product, the Zimmer NexGen CR Flex, representing the quality to health care professionals, the FDA, Plaintiff Ali Elbaneh, and the public in such a way as to induce its purchase or use, thereby making an express warranty that the Zimmer NexGen CR Flex would conform to the representations. More specifically, Defendants represented that the Zimmer NexGen CR Flex was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff's condition.

89. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

90. The Zimmer NexGen CR Flex did not conform to the representations made by Defendants in that the Zimmer NexGen CR Flex was not safe and effective, was not safe and effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

91. At all relevant times, Plaintiff used the Zimmer NexGen CR Flex for the purpose and in the manner intended by Defendants.

92. Plaintiff and Plaintiff's physician, by the use of reasonable care, would not have discovered the breached warranty and realized its danger.

93. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

94. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer NexGen CR Flex, Plaintiff was implanted with Zimmer NexGen CR Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

95. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI

(BREACH OF IMPLIED WARRANTY)

96. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

97. The Zimmer NexGen CR Flex was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer NexGen CR Flex minimally safe for its expected purpose.

98. At all relevant times, Plaintiff used the Zimmer NexGen CR Flex for the purpose and in the manner intended by Defendants.

99. Plaintiff and Plaintiff's physician, by the use of reasonable care would not have discovered the breached warranty and realized its danger.

100. The breach of the warranty was a substantial factor in bringing about Plaintiff's injuries.

101. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer NexGen CR Flex, Plaintiff was implanted with Zimmer NexGen CR Flex and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

102. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI

(FRAUDULENT MISREPRESENTATION)

103. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

104. Defendant falsely and fraudulently represented to the medical and psychiatric community and to the plaintiff and the public in general, that the Zimmer NexGen CR Flex had been tested and found to be safe and effective for the use in total knee arthroplasty.

105. Defendant knew, or should have known, that its representations were false yet it willfully, wantonly and recklessly disregarded its obligation to provide truthful representations regarding the safety and risks of Zimmer NexGen CR Flex to consumers, including plaintiff, and the medical and orthopedic communities.

106. Defendant's representations were made with the intent of defrauding and deceiving plaintiff, other consumers, generally, and the medical and psychiatric communities, particularly, with the intent of encouraging and inducing sales of Zimmer NexGen CR Flex.

107. Defendant knowingly, consciously, and deliberately placed its financial gain above the rights and safety plaintiff and other consumers.

108. Defendant's fraudulent representations evinced its callous, reckless, willful, and depraved indifference to the health, safety, and welfare of consumers, including plaintiff.

109. Plaintiff was unaware of the falsity of Defendant's representations and reasonably relied upon Defendant's representations, thereby developing prosthetic loosening and enhanced risk of developing additional severe and permanent injuries in the future.

110. As a direct and proximate result of Defendant's fraudulent misrepresentations, plaintiff developed prosthetic loosening and was caused to suffer severe and permanent injuries, pain, and mental anguish, including diminished enjoyment of life, and fear of developing other harmful conditions including, but not limited to, another revision surgery.

111. In addition, Defendant's conduct in the marketing, advertising, promotion, distribution, and sale of Zimmer NexGen CR Flex was committed with knowing, conscious, willful, wanton, and deliberate disregard for the value of human life, and the rights and safety of consumers such as plaintiff, thereby entitling plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

112. As a direct and proximate result of the fraudulent misrepresentation and as a result of the defendant's actions and/or inactions as set forth in this complaint, plaintiff is caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium and to incur related expenses, including, but not

limited to, additional surgeries, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiffs demands all damages to which the plaintiff is entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT VII

(FRAUDULENT CONCEALMENT)

113. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

114. At all relevant times, Defendant concealed or omitted material information regarding the safety of Zimmer NexGen CR Flex from consumers, including plaintiff, and the medical and psychiatric communities.

115. Defendant knew, or was reckless in not knowing, that Zimmer NexGen CR Flex posed significant risks of causing severe and permanent injuries, and elected not to advise the medical and psychiatric communities, plaintiff, or other consumers of Zimmer NexGen CR Flex's risks, and consequently placed its profits above the safety of plaintiff and other consumers.

116. In its representations, Defendant fraudulently concealed and intentionally omitted material information about Zimmer NexGen CR Flex's dangers from consumers, including plaintiff.

117. Defendant knew, or was reckless in not knowing, that Zimmer NexGen CR Flex causes dangerous prosthetic loosening and other severe and permanent injuries.

118. Defendant had sole access to material facts concerning the dangers and unreasonable risks of Zimmer NexGen CR Flex.

119. Defendant willfully concealed material information regarding the dangers of Zimmer NexGen CR Flex to induce consumers, including plaintiff, to use Zimmer NexGen CR Flex. Defendant's concealment of the defective nature of Zimmer NexGen CR Flex and its dangerous risks caused plaintiff to suffer damages.

120. Defendant was under a duty to disclose to plaintiff, other consumers, and the medical and orthopedic communities the defective nature of Zimmer NexGen CR Flex, and the risks and dangers associated with its use.

121. As a direct and proximate result of Defendant's fraudulent concealment, plaintiff developed prosthetic loosening and was caused to suffer severe and permanent injuries, pain, and mental anguish, including diminished enjoyment of life, and fear of developing other harmful conditions including additional surgeries.

122. In addition, Defendant's conduct in the marketing, advertising, promotion, distribution, and sale of Zimmer NexGen CR Flex was committed with knowing, conscious, willful, wanton, and deliberate disregard for the value of human life, and the rights and safety of consumers such as plaintiff, thereby entitling plaintiff to punitive damages so as to punish Defendant and deter it from similar conduct in the future.

123. As a direct and proximate result of the fraudulent concealment of the defendant's actions and/or inactions as set forth in this complaint, plaintiff was caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution

in earning capacity and/or other costs as proof will show, and the plaintiff demands all damages to which the plaintiff is entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT VIII

(NEGLIGENT MISREPRESENTATION)

124. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

125. Defendant, in addition to knowing misrepresentations, made misrepresentations without any reasonable grounds for believing its statements to be true to plaintiff, other patients, and the medical and orthopedic communities.

126. Defendant, through its misrepresentations, intended to induce justifiable reliance by plaintiff, other patients, and the medical and psychiatric communities.

127. Defendant, through its marketing campaign and communications with treating physicians or orthopedists, was in a relationship so close to that of plaintiff and other patients that it approaches and resembles privity.

128. Defendant owes a duty to the medical and psychiatric communities, plaintiff, and other consumers, to conduct appropriate and adequate studies and tests for all its products, including Zimmer NexGen CR Flex, and to provide appropriate and adequate information and warnings.

129. Defendant failed to conduct appropriate or adequate studies for Zimmer NexGen CR Flex.

130. Defendant failed to exercise reasonable care by failing to conduct studies and tests of Zimmer NexGen CR Flex. -

131. As a direct and proximate result of Defendant's negligent misrepresentations, plaintiff developed diabetes and was caused to suffer severe and permanent injuries, pain, and mental anguish, including diminished enjoyment of life, and fear of developing other harmful conditions including, but not limited to, additional surgeries.

132. As a direct and proximate result of defendant's negligent misrepresentations and as a result of the defendant's actions and/or inactions as set forth in this complaint, plaintiff was caused to suffer damages, including, but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiff demands all damages to which the plaintiff is entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

COUNT IX

(VIOLATION OF NEW YORK GENERAL BUSINESS LAW SECTION 349)

133. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

134. Defendant engaged in commercial conduct by selling Zimmer NexGen CR Flex.

135. Defendant misrepresented and omitted material information regarding Zimmer NexGen CR Flex by failing to disclose known risks.

136. By failing to disclose the known dangers and risks of Zimmer NexGen CR Flex, Defendant engaged in unfair and deceptive consumer-oriented acts.

137. Reasonable consumers, including plaintiff, were injured by Defendant's unfair and deceptive acts.

138. As a direct and proximate result of Defendant's conduct, plaintiff has suffered actual damages and requests an award of damages against Defendant, as authorized by New York General Business Law § 349, et seq. Plaintiff is entitled to statutory damages, punitive damages, costs and reasonable attorneys' fees, plus disgorgement of any profits Defendant earned as a result of its violations of law.

COUNT VII

(LOSS OF CONSORTIUM)

139. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

140. Plaintiff's spouse, Subhia Elbaneh, was at all times relevant herein married to plaintiff.

141. By reason of the foregoing, plaintiffs spouse has necessarily paid and has become liable to pay for medical aid, treatment, attendance, and for medications, and will necessarily incur further expenses of a similar nature in the future.

142. By reason of the foregoing, plaintiff's spouse has been caused, presently and in the future the loss of plaintiffs husband's companionship, services, society and the ability of said plaintiffs spouse in said respects has been impaired, and depreciated, and the marital association between husband and wife has been altered, and as such the plaintiffs spouse has been caused great mental anguish and suffering.

143. Plaintiffs demand judgment against each defendant individually and/or jointly for compensatory damages and punitive damages together with interest, costs of suit and attorneys' fees and such other relief as the Court deems proper.

COUNT XI

(PUNITIVE DAMAGES)

144. Plaintiff repeats, reiterates, and realleges each and every allegation contained in this Complaint with the same force and effect as if fully set forth herein.

145. Defendant's conduct in manufacturing, marketing, selling, distributing, testing and submitting for FDA approval was outrageous, that is, done with bad motives and/or with a reckless indifference to the interest of others, including plaintiff, the consuming public, health care professionals and the FDA.

146. As a direct and proximate result of the defendants' outrageous conduct, plaintiff was caused to suffer damages, including but not limited to, pain, suffering, and loss in the quality of life, loss of society and comfort, loss of consortium, and to incur related expenses, including, but not limited to, prescription medicines, medical hospital and nursing costs as well as loss of earnings, diminution in earning capacity and/or other costs as proof will show, and the plaintiff demands all damages to which plaintiff is entitled under the law in an amount deemed fair and reasonable, including interest, costs, attorney fees, and punitive damages.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

147. Compensatory damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all his injuries and damages, both past and present;

148. Special damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of his injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for

past and future rehabilitation and/or home health care, lost income, permanent disability, including permanent instability and loss of balance, and pain and suffering.

- 149. Double or triple damages as allowed by law;
- 150. Attorneys' fees, expenses, and costs of this action;
- 151. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
- 152. Such further relief as this Court deems necessary, just, and proper.

JURY DEMAND

Plaintiff demands a trial by jury of all claims asserted in this Complaint.

Dated: June 3, 2011

Respectfully submitted,



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